DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

5/1952d

WARNING LETTER
VIA FEDERAL EXPRESS

NOV 16 2001

Ms. Ivana Korcakova
Quality Assurance Manager
Bioster a.s.
CZ-664 71 Tejny 621
Veverska Bityska
Czech Republic

Dear Ms. Korcakova:

During the Food and Drug Administration's (FDA) inspection of your firm, Bioster a.s. at CZ-664 71 Tejny 621, Veverska Bityska, Czech Republic, on August 29, 2001, our investigator determined that your firm is a contract sterilizer and control-testing laboratory for the [redacted] are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated, within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packaging, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

> Failure to establish and maintain procedures to adequately control environmental conditions where environmental conditions could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR§ 820.70(c). For example, your sterility-testing laboratory is not pressurized and has no atmospheric breaks. Employees were observed entering the testing room without protective clothing. Wooden matches and ashtrays were observed at the Class 100 workstation. Extreme levels of dust were observed in the exhaust fans situated above the door of the testing room. Particulate testing is conducted only on a quarterly basis and settling plates are only used to monitor microbiological levels of the media preparation area and laminar flow workstation. Additionally, there are no sanitizing stations or air conditioning in the area.

We acknowledge the receipt of your written response to the FD-483 dated September 19, 2001. Your response suggested two possible corrective actions: building new clean rooms with two laminar flow boxes with construction starting in February or March of 2002, and modifying current sterility testing laboratory procedures; **or** sub-contracting a new sterility bioburden testing laboratory for testing services. Until deficiencies found at your firm are corrected and verified by FDA, you are considered an unacceptable supplier for sterility testing laboratory services.

Therefore, the first corrective action suggested is not acceptable unless you plan to cease all testing services until the rooms are completed. The second action, involving subcontracting a new facility, appears to be more feasible.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You must also promptly initiate permanent corrective, and preventive action on your Quality System.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action initiated by FDA without further notice. This action may be detention of the above-mentioned device without physical examination upon entry into the United States.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Please address your response and any questions to Paul F. Tilton, Chief, OB/GYN, Gastroenterology and Urology Branch, at the letterhead address. Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Sharon Murrain-Ellerbe at the letterhead address or at (301) 594-4616 or FAX (301)594-4638.

Sincerely yours,

Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health